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Drug Utilization Review Board Meeting Agenda, Open Session July 8, 2015 10:00 a.m. – 2:00 p.m.

Meeting Location

HP Enterprise Services, Capital Room 6700 SW Topeka Blvd, Bldg. 283 J, Topeka, KS 66619

Board Members

James Backes, PharmD Russell Scheffer, MD
Tim Heston, DO Roger Unruh, DO
John Kollhoff, PharmD Moneeshindra Mittal, MD
Judy McDaniel Dowd, PA-C

KDHE-DHCF Staff

Kelley Melton, PharmD Liane Larson, PharmD

HP Enterprise Services/HID Staff

Ariane Casey, PharmD Karen Kluczykowski, RPh Nancy Perry, RN

MCO Staff

Jonalan Smith, PharmD, FASCP, **Sunflower State Health Plan** Jennifer Murff, RPh, **UnitedHealthcare Community Plan** Lisa Todd, RPh, **Amerigroup**

- I. CALL TO ORDER
 - A. Announcements
- II. OLD BUSINESS
 - A. Review and Approval of April 8, 2015 Meeting Minutes
- III. NEW BUSINESS
 - A. New Preferred Drug List (PDL) Classes
 - 1. Anticoagulants

At the May 2015 PDL meeting, the committee approved the addition of the Anticoagulants to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.

- i. Non-Preferred PDL PA Criteria
- ii. *Public Comment
- iii. Board Discussion

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2. Hepatitis C Antiviral Agent Regimens

At the May 2015 PDL meeting, the committee approved the addition of the Hepatitis C Antiretroviral Agent Regimens to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.

- i. Non-Preferred PDL PA Criteria
- ii. *Public Comment
- iii. Board Discussion

3. Injectable Methotrexate

At the May 2015 PDL meeting, the committee approved the addition of the Injectable Methotrexate to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.

- i. Non-Preferred PDL PA Criteria
- ii. *Public Comment
- iii. Board Discussion

4. Phosphate Binder Agents

At the May 2015 PDL meeting, the committee approved the addition of the Phosphate Binder Agents to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.

- i. Non-Preferred PDL PA Criteria
- ii. *Public Comment
- iii. Board Discussion

5. Topical Acne Products

At the May 2015 PDL meeting, the committee approved the addition of the Topical Acne Products to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.

- i. Non-Preferred PDL PA Criteria
- ii. *Public Comment
- iii. Board Discussion

6. **Topical Lice Treatments**

At the May 2015 PDL meeting, the committee approved the addition of the Topical Lice Treatments to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents.

- i. Non-Preferred PDL PA Criteria
- ii. *Public Comment
- iii. Board Discussion

B. Revised Prior Authorization (PA) Criteria

1. Byetta® (exenatide)

Byetta is a glucagon-like peptide 1 (GLP-1) receptor agonist indicated for the treatment of type 2 diabetes mellitus. Prior authorization criteria were initially approved in April 2010. Since that time, a contraindication for use in patients with a personal or family history of medullary thyroid carcinoma has been added. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

2. Victoza® (liraglutide)

Victoza is a glucagon-like peptide 1 (GLP-1) receptor agonist indicated for the treatment of type 2 diabetes mellitus. Prior authorization criteria were last revised in October 2012. Since that time, contraindications for use in patients with a personal or family history of medullary thyroid carcinoma or a personal history of multiple endocrine neoplasia syndrome type 2 (MENS2) has been added. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

3. Olysio® (simeprevir)

Olysio is a hepatitis C protease inhibitor indicated for the treatment of genotype 1 chronic hepatitis C. Prior authorization criteria were last revised in April 2015. Since that time, a warning has been issued encompassing the risk of hepatic decompensation, including fatalities, in patients with pretreatment advanced and/or decompensated cirrhosis. The prior authorization criteria are being revised to ensure appropriate use.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

4. Herceptin® (trastuzumab)

Herceptin is approved for the treatment of breast cancer and gastric cancer. Prior authorization criteria were initially approved in October 2013. Since that time, clarification that patients being treated for adjuvant breast cancer should not be exceed a duration of 12 months. Patients must not be or become pregnant for at least 7 month post-treatment. The prior authorization criteria are being revised to ensure appropriate use.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

5. Lupron® (leuprolide)

Lupron is approved for the treatment of central precocious puberty (CPP) in children. Prior authorization criteria were initially approved in April 2011. The prior authorization criteria are being revised to include other commonly used hormone evaluations for the diagnosis of CPP.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

6. Growth Hormones (Zomacton® [somatropin])

Prior authorization criteria for human growth hormones were last revised in July 2014. Since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Zomacton, a new brand name for Tev-Tropin.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

7. Weight Loss Drugs (Contrave® [naltrexone/bupropion])

Prior authorization criteria for weight loss drugs were last revised in April 2015. Response to Contrave is to be evaluated after 12 weeks of maintenance therapy; the maintenance dose is not reached until after 3 weeks of therapy. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

8. Weight Loss Drugs (phentermine products)

Prior authorization criteria for weight loss drugs were last revised in April 2015. Prior authorization is being proposed to extend the approval duration of phentermine. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

9. Long-Acting Beta-Agonists (Striverdi Respimat® [olodaterol])

Prior authorization criteria for long-acting beta-agonists were initially approved in October 2011. Since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Striverdi Respimat, indicated for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adults.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

10. Promacta® (eltrombopag)

Prior authorization criteria for Promacta was last revised in October 2014. Since that time, it has become approved in pediatrics at least 6 years of age with the diagnosis of idiopathic thrombocytopenia (ITP). The prior authorization criteria is being revised to include ages 6-17 years for this indication.

- i. Revised PA Criteria
- ii. *Public Comment
- iii. Board Discussion

C. New Prior Authorization (PA) Criteria

1. Jakafi® (ruxolitinib)

Jakafi is a Janus-associated kinase inhibitor indicated for the treatment of myelofibrosis. It is also indicated for polycythemia vera in patients who have had an inadequate response to or intolerance to hydroxyurea. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

2. Farydak® (panobinostat)

Farydak is a histone deacetylase inhibitor indicated for the treatment of multiple myeloma in patients who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

3. Natpara® (parathyroid hormone)

Natpara is a parathyroid hormone analog indicated to control hypocalcemia as an adjunct to calcium and vitamin D in patients with hypoparathyroidism. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

4. Jadenu® (deferasirox)

Jadenu is a chelating agent indicated for the treatment of chronic iron overload. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

D. Miscellaneous Items

1. Opana® (oxymorphone)

Opana is an opioid analgesic available in an immediate-release tablet and long-acting tablet. The long-acting formulation was recently reformulated to deter abuse. Recent reports of Opana abuse, due to the new formulation, have risen and it may be contributing to the spread of human immunodeficiency virus (HIV). Background information and utilization data are being presented for review of the Opana prior authorization criteria.

- i. *Public Comment
- ii. Board Discussion

2. Mental Health Dose Optimization

Starting July 2015, the MCOs will be able to require that their patients are on the most efficient medication regimens for select mental health medications. If a patient has had long-term use of a higher quantity of a lower strength, they will be switched to a lower quantity of a higher strength (e.g., if a patient is on 2 tablets of Abilify 5 mg per day, the patient will be switched to a single dose of Abilify 10 mg per day).

- i. *Public Comment
- ii. Board Discussion

3. Medication Hold Process

The pharmacy program was given authority to implement a medication hold process for new drugs. For a new drug that enters the market that will require clinical PA criteria, the drug can be placed into a 'hold' status until it has been taken to the next upcoming DUR Board for review. Should a patient need access to the medication in the interim, the patient will be able to request a review of their claim based on compliance with the drug's package insert.

- i. *Public Comment
- ii. Board Discussion

4. Fee-for-Service Retrospective Drug Utilization Review Topic Selections

The DUR Board will select topics for the two (2) RDUR intervention topics between July and December 2015.

- i. Topic Presentations
- ii. Board Discussion

IV. OPEN PUBLIC COMMENT

V. ADJOURN

Lunch will be provided for the DUR Board members.

The next DUR Board meeting is scheduled for October 14, 2015.

^{*}Public comment is limited to five minutes per product; additional time will be allowed at the DUR Board's discretion. Informal comments will be accepted from members of the audience at various points in the agenda.